INPLASY PROTOCOL

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None declared.

Efficacy of Jinshuibao as an adjuvant treatment for chronic renal failure in China: a meta-analysis

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Review question / Objective: **Our aim is to systematically evaluate the efficacy of JSB for the treatment of CRF in Chinese patients, and to provide evidence-based medical advice for clinical practice.**
Condition being studied: **Chronic renal failure (CRF) is a clinical syndrome with progressive renal function decline until failure on the basis of various chronic kidney diseases. The main clinical manifestations are the decline of glomerular filtration rate, retention of metabolites, disorders of water and electrolyte and imbalance of acid-base balance. [1-2] It has many complications and poor prognosis, which seriously affects the quality and the span of life in patients.[3] The incidence of CRF is increasing year by year and has become a major public health problem worldwide.[4] Epidemiological survey shows that chronic kidney disease has become the sixth cause of death in the world.[5] The prevalence rate of chronic kidney diseases among American adults is high at 15.1%, and the prevalence of chronic kidney diseases in China is about 10.8%.[6] At present, there is no effective treatment for CRF all over the world, and the only interventional treatment can be carried out, which cannot completely prevent the development of the disease. Therefore, it is particularly important to actively seek effective therapeutic drugs to alleviate CRF and delay the renal failure.Chronic renal failure (CRF) is a clinical syndrome with progressive renal function decline until failure on the basis of various chronic kidney diseases.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 May 2023 and was last updated on 28 May 2023 (registration number INPLASY202350105).

INTRODUCTION

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METHODS

Search strategy: We will search articles in eight databases including PubMed, EMBASE, Cochrane Library, Web of science, China Biology Medicine disc (CBM), Wanfang, Chinese Scientific Journal Database (VIP) and China National Knowledge Infrastructure (CNKI) form inception to March 31, 2023. Retrieval approach: the search terms were chronic renal failure, chronic kidney failure, renal failure, chronic, chronic renal failure, chronic renal insufficiency, Jinshuibao, random, etc. Retrieval approach: the search terms were chronic renal failure, chronic kidney failure, renal failure, chronic, chronic renal failure, chronic renal insufficiency, Jinshuibao, random, etc.

Participant or population: Patients with CRF were not limited in sex, age, primary disease and clinical stage.

Intervention: The control group received CT (such as high-quality low protein, low salt, low fat and low phosphorus diet, supplement of trace elements and multivitamins, control of blood sugar and blood pressure, correction of water and electrolyte disorders and acid-base imbalance, correction of anemia, anti-infection treatment, etc.) or other drugs for symptomatic treatment, while the experimental group was treated with Chinese patent medicine JSB on the basis of the control group.

Comparator: The control group received CT (such as high-quality low protein, low salt, low fat and low phosphorus diet, supplement of trace elements and multivitamins, control of blood sugar and blood pressure, correction of water and electrolyte disorders and acid-base imbalance, correction of anemia, anti-infection treatment, etc.) or other drugs for symptomatic treatment.

Study designs to be included: Randomized controlled trials (RCTs) which compared JSB combined with conventional treatment (CT) with CT alone in CRFclinical randomized controlled trials.

Eligibility criteria: The Inclusion criteria were as follows.1.Study design: The study must be a randomized controlled study.2.Subjects : All subjects were that the patients with CRF were not limited in sex, age, primary disease and clinical stage;3.Intervention measures: The control group received CT (such as high-quality low protein, low salt, low fat and low phosphorus diet, supplement of trace elements and multivitamins, control of blood sugar and blood pressure, correction of water and electrolyte disorders and acid-base imbalance, correction of anemia, anti-infection treatment, etc.) or other drugs for symptomatic treatment, while the experimental group was treated with Chinese patent medicine JSB on the basis of the control group.2.2.2. The Exclusion criteria were as follows.1.Non-clinical trials, review papers, meta-analyses, meeting abstracts, case reports. 2.Inappropriate interventions on experimental or control group.3.Alternative treatments such as dialysis or kidney transplantation were

applied.4.Clinical research with unclear observation indicators, duplicate research, studies without sufficient available data.5.Not RCTs.

Information sources: PubMed, EMBASE, Cochrane Library, Web of science, China Biology Medicine disc (CBM), Wanfang, Chinese Scientific Journal Database (VIP) and China National Knowledge Infrastructure (CNKI).

Main outcome(s): Total effective rate.

Additional outcome(s): Blood urea nitrogen (BUN), Serum creatinine (Scr), Creatinine clearance rate (Ccr), 24-hour urine protein (24 hpro), Uric acid (UA). Blood biochemical indicators: Albumin (Alb), Hemoglobin (Hb). Microinflammatory index: Tumor necrosis factor-α (TNF-α), Interleukin-6 (IL-6), High-sensitivity C-reactive protein (hs-CRP).

Quality assessment / Risk of bias analysis: The quality evaluation standard of randomized controlled trials adopts the bias risk evaluation standard recommended by Revman 5.4: selection bias (random sequence generation and allocation concealment), performance bias, detection bias, attrition bias, reporting bias and other bias. Each project is evaluated according to low risk, unknown risk and high risk.

Strategy of data synthesis: Review Manager5.4 software recommended by Cochrane collaboration network were used for data analysis. The χ2 test was used to analyze the heterogeneity of the included RCTs. When $P > 0.10$ and $I2 < 50\%$, it indicates that the RCTs is homogenous or the heterogeneity can be ignored, so the fixed effect model was adopted. When $P \leq 0.10$ or $I2 \geq 50\%$, which indicates that the included study is highly heterogeneous, and the random effect model should be used for meta-analysis. The total effective rate in this study was counting data, and relative risk (RR) was used for statistical analysis. BUN, Scr, Ccr, 24 hpro, UA, Alb, Hb, TNF-α, IL-6 and hs-CRP were measured data, which were analyzed by weighted mean difference (WMD). All analyses were expressed with 95% Confidence interal (95% CI).

Subgroup analysis: This study conducted a subgroup analysis based on the course of treatment, with a course of treatment of 4 weeks, 8 weeks, and 12 weeks, respectively.

Sensitivity analysis: Sensitivity analysis was also conducted to evaluate the effect of the individual study data.

Language restriction: No.

Country(ies) involved: China.

Keywords: Chronic renal failure; Jinshuibao; System evaluation; Meta-analysis.

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